Kite Pharma, a Gilead Company announced the assignment of a product-specific Q-code for TECARTUS® (brexucabtagene autoleucel). The Centers for Medicare & Medicaid Services (CMS) has assigned the Healthcare Common Procedure Coding System (HCPCS) code Q2053 to TECARTUS with the effective date of April 1, 2021.[1] This information is being provided so you can integrate this code and billing unit into your claims-processing system and consider it for inclusion in medical coverage policy coding criteria as appropriate.

TECARTUS was approved by the US Food and Drug Administration on July 24, 2020. TECARTUS is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).[2] This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Please see Important Safety Information below and the full Prescribing Information for TECARTUS.

Product Name	Temporary Drug-Specific HCPCS Code[1]	CMS Long Descriptor[1]	Effective Date[1]
TECARTUS® (brexucabtagene autoleucel)	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	April 1, 2021

TECARTUS is supplied as an infusion bag. Each single infusion bag contains a suspension of CAR T cells in ~68 mL.[3]

National Drug Code (NDC): 71287-**0**219-01*[3]

*NDC has been "zero-filled" to ensure creation of an 11-digit code that meets Health Insurance Portability and Accountability Act (HIPAA) standards.[4] The zero-fill location is indicated in bold.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITIES

- **Cytokine Release Syndrome (CRS), including life-threatening reactions, occurred in patients receiving TECARTUS. Do not administer TECARTUS to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.**
- **Neurologic toxicities, including life-threatening reactions, occurred in patients receiving TECARTUS, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with TECARTUS. Provide supportive care and/or corticosteroids as needed.**
- **TECARTUS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program.**

Please see additional Important Safety Information below.

Using an established treatment process, TECARTUS is provided as a single-dose, one-time infusion followed by at least 7 days of onsite monitoring.[3]

Referring Physician: The patient is sent to an Authorized Treatment Center (ATC) for CAR T-cell therapy.[3]

Leukapheresis: White blood cells are collected in the outpatient setting at an ATC.[3]

Manufacturing (during the ZUMA-2 trial, median time from leukapheresis to product delivery was **15 days**): T cells are isolated from the peripheral blood and shipped to Kite, where cell therapy is produced and returned to the ATC.[3,5]

Lymphodepleting Chemotherapy Pre-treatment: The patient receives a 3-day outpatient lymphodepleting chemotherapy regimen on the fifth, fourth, and third day prior to the scheduled infusion of their TECARTUS. The lymphodepleting regimen consists of cyclophosphamide 500 mg/m^2 intravenous (IV) and fludarabine 30 mg/m^2 IV.[3]

TECARTUS Infusion: Following premedication with acetaminophen and diphenhydramine, TECARTUS is infused into the patient at the ATC.[3†]

†Premedicate with acetaminophen and diphenhydramine or another H1-antihistamine approximately 30 to 60 minutes prior to TECARTUS infusion.[3]

Monitoring: Monitor patients daily for at least 7 days at the ATC following infusion of TECARTUS for signs and symptoms of cytokine release syndrome (CRS), neurologic events, and any other side effects that may occur. Post-discharge, patients remain within proximity of the ATC for the remainder of at least the first 4 weeks post-infusion.[3]

Return to Referring Physician: Patients receive routine monitoring for long-term adverse events.[3]

IMPORTANT SAFETY INFORMATION (continued)

Cytokine Release Syndrome (CRS), including life-threatening reactions, occurred following treatment with TECARTUS. In ZUMA-2, CRS occurred in 91% (75/82) of patients receiving TECARTUS, including ≥ Grade 3 CRS in 18% of patients. Among the patients who died after receiving TECARTUS, one had a fatal CRS event. The median time to onset of CRS was three days (range: 1 to 13 days) and the median duration of CRS was ten days (range: 1 to 50 days). Among patients with CRS, key manifestations (>10%) included fever (99%), hypotension (60%), hypoxia (37%), chills (33%), tachycardia (37%), headache (24%), fatigue (19%), nausea (13%), alanine aminotransferase increased (13%), aspartate aminotransferase increased (12%), and diarrhea (11%). Serious events associated with CRS included hypotension, fever, hypoxia, acute kidney injury, and tachycardia.

Ensure that a minimum of two doses of tocilizumab are available prior to infusion of TECARTUS. Following infusion, monitor patients for signs and symptoms of CRS daily for at least seven days at the certified healthcare facility, and for four weeks thereafter. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. At the first sign of CRS, institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids as indicated.

Neurologic Toxicities, including those that were life-threatening, occurred following treatment with TECARTUS. In ZUMA-2, neurologic events occurred in 81% of patients, 37% of whom experienced Grade ≥3 adverse reactions. The median time to onset for neurologic events was six days (range: 1 to 32 days). Neurologic events resolved for 52 out of 66 (79%) patients with a median duration of 21 days (range: 2 to 454 days). Three patients had ongoing neurologic events at the time of death, including one patient with serious encephalopathy. The remaining unresolved neurologic events were either Grade 1 or Grade 2. Fifty-four (66%) patients experienced CRS by the onset of neurological events. Five (6%) patients did not experience CRS with neurologic events and eight patients (10%) developed neurological events after the resolution of CRS. 85% of all treated patients experienced the first CRS or neurological event within the first seven days after TECARTUS infusion.

The most common neurologic events (>10%) included encephalopathy (51%), headache (35%), tremor (38%), aphasia (23%), and delirium (16%). Serious events including encephalopathy, aphasia, and seizures occurred.

Monitor patients daily for at least seven days at the certified healthcare facility and for four weeks following infusion for signs and symptoms of neurologic toxicities and treat promptly.

REMS Program: Because of the risk of CRS and neurologic toxicities, TECARTUS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program which requires that:

- Healthcare facilities that dispense and administer TECARTUS must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of two doses of tocilizumab are available for each patient for infusion within two hours after TECARTUS infusion, if needed for treatment of CRS.
- Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense, or administer TECARTUS are trained in the management of CRS and neurologic toxicities. Further information is available at www.YescartaTecartusREMS.com or 1-844-454-KITE (5483).

Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylaxis, may occur due to dimethyl sulfoxide (DMSO) or residual gentamicin in TECARTUS.

Severe Infections: Severe or life-threatening infections occurred in patients after TECARTUS infusion. In ZUMA-2, infections (all grades) occurred in 56% of patients. Grade 3 or higher infections, including bacterial, viral, and fungal infections, occurred in 30% of patients.
TECARTUS should not be administered to patients with clinically significant active systemic infections. Monitor patients for signs and symptoms of infection before and after infusion and treat appropriately. Administer prophylactic antimicrobials according to local guidelines.

Febrile neutropenia was observed in 6% of patients after TECARTUS infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care as medically indicated.

In immunosuppressed patients, including those who have received TECARTUS, life-threatening and fatal opportunistic infections, including disseminated fungal infections (eg, candida sepsis and aspergillus

infections) and viral reactivation (eg, human herpes virus-6 [HHV-6] encephalitis and JC virus progressive multifocal leukoencephalopathy [PML]) have been reported. The possibility of HHV-6 encephalitis and PML should be considered in immunosuppressed patients with neurologic events and appropriate diagnostic evaluations should be performed.

Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients treated with drugs directed against B cells. Perform screening for HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing.

Prolonged Cytopenias: Patients may exhibit cytopenias for several weeks following lymphodepleting chemotherapy and TECARTUS infusion. In ZUMA-2, Grade ≥3 cytopenias not resolved by Day 30 following TECARTUS infusion occurred in 55% of patients and included thrombocytopenia (38%), neutropenia (37%), and anemia (17%). Monitor blood counts after infusion.

Hypogammaglobulinemia and B-cell aplasia can occur in patients receiving treatment with TECARTUS. In ZUMA-2, hypogammaglobulinemia occurred in 16% of patients. Monitor immunoglobulin levels after treatment with TECARTUS and manage using infection precautions, antibiotic prophylaxis, and immunoglobulin replacement. The safety of immunization with live viral vaccines during or following TECARTUS treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least six weeks prior to the start of lymphodepleting chemotherapy, during treatment, and until immune recovery following treatment with TECARTUS.

Secondary Malignancies may develop. Monitor life-long for secondary malignancies. In the event that it occurs, contact Kite at 1-844-454-KITE (5483) to obtain instructions on patient samples to collect for testing.

Effects on Ability to Drive and Use Machines: Due to the potential for neurologic events, including altered mental status or seizures, patients are at risk for altered or decreased consciousness or coordination in the 8 weeks following TECARTUS infusion. Advise patients to refrain from driving and engaging in hazardous activities, such as operating heavy or potentially dangerous machinery, during this period.

Adverse Reactions: The most common (incidence ≥ 20%) were pyrexia, CRS, hypotension, encephalopathy, fatigue, tachycardia, arrhythmia, infection – pathogen unspecified, chills, hypoxia, cough, tremor, musculoskeletal pain, headache, nausea, edema, motor dysfunction, constipation, diarrhea, decreased appetite, dyspnea, rash, insomnia, pleural effusion, and aphasia. Serious adverse reactions occurred in 66% of patients. The most common serious adverse reactions (> 2%) were encephalopathy, pyrexia, infection – pathogen unspecified, CRS, hypoxia, aphasia, renal insufficiency, pleural effusion, respiratory failure, bacterial infections, dyspnea, fatigue, arrhythmia, tachycardia, and viral infections.

Please see the full Prescribing Information, including **BOXED WARNING** and Medication Guide, for TECARTUS.

For more information, please visit TECARTUS.com/hcp.